

REMARKS

I. Preliminary Comments

The above-identified case is directed to the treatment of pain caused by otitis media by the topical administration of DNA in a manner so as to not effect gene transfer. The claims were previously allowed but prosecution was then reopened. Applicant thanks the Examiner for the withdrawal of a previous rejection under 35 U.S.C. 112 (second paragraph) for indefiniteness but claims 15-19 remain rejected on the basis that the disclosure fails to comply with the enablement requirement under 35 U.S.C. 112 (first paragraph).

II. Outstanding Rejections

Claims 15-19 stand rejected under 35 U.S.C. §112 (first paragraph) for failure to comply with the enablement requirement.

III. Patentability Arguments

The rejection of Applicant's pain reduction claims on the basis that the disclosure fails to enable a reduction in bacteria or virus numbers should be withdrawn because Applicant's invention is not an antibacterial invention and there should be no requirement to establish that the therapy reduces numbers of bacteria or viruses. While otitis media is frequently secondary to infection, the elimination or treatment of infection is neither necessary nor sufficient to treat the symptoms of otitis media.

Applicant does not dispute that otitis media can result from bacterial or viral infection but argues that the symptoms of otitis media are thought to be the consequence of an inflammatory response which may or may not be associated with an infection. Moreover, even when the otitis media is associated with infection, the inflammatory response may not be immediately relieved when the infection is eliminated.

Otitis media can be classified as acute otitis media which is otitis media in the presence of infection and serous otitis media (also known as "otitis media with effusion," OME) which is "without signs of infection." (See Managing Otitis Media With Effusion in Young Children, Pediatrics, Vol. 94, No. 5 November 1995 attached as Appendix B in the

Response dated March 8, 2004) Similarly, Taber's Cyclopedic Medical Dictionary Ed 16 1989 [submitted herewith as Appendix A] states that otitis media with effusion is "characterized by the secretion of a serous fluid into the middle ear due to obstruction of the Eustachian tube" and that "[t]he serous fluid may be sterile or it may be infected with pathogenic organisms. The cause of the obstruction may be enlarged adenoid tissue in the pharynx, inflammation in the pharynx, tumors in the pharyngeal area, or allergy." (emphasis supplied) Thus, Applicant has provided evidence that otitis media can occur and persist in the absence of virus or bacteria!

In response to the Examiner's implied assertion that "not treating otitis media with antibiotics" was unknown at the time of filing, Applicants submit herewith Buchem, J. Royal College of General Practitioners, p. 367 August 1987 and Buchem et al., British Medical J. 290: 1033-1037 (1985) (attached hereto as Appendix B) the former stating that "over 90% of such children [having acute otitis media] do not need antibiotics at all."

Applicants therefore traverse the proposition that the administration of DNA topically into the ear does not effect "a change in symptoms" and dismiss the relevance of whether such administration should affect the amount of pathogen in the ear.

IV. Conclusion

For the reasons set out, Applicants believe that each of claims 15-19 are in condition for allowance. Should the Examiner wish to discuss any issue of form or substance he is encouraged to contact the undersigned attorney at the number listed below.

Dated: October 4, 2007

Respectfully submitted,

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